REMARKS

I. Status of the Application

Claims 1-37 are presently pending in the application. Claims 1, 6, 21 and 22 have been amended. Applicant gratefully acknowledges that claims 27 and 28 have been indicated allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-8, 11, 12, 15-20, 31-33 and 35-37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., U.S. Patent No. 4,655,777. Claims 1, 13, 14, 29 and 34 stand rejected under 35 U.S.C. §102(e) as being anticipated by Ylanen et al., U.S. Patent No. 6,248,344. Claims 1, 9, 10, 21 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., 4,655,777. Claims 1, 6 and 23-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., 4,655,777, in view of Tormala et al., U.S. Patent No. 6,350,284.

Applicant has amended the claims to more clearly define and distinctly characterize Applicant's novel invention. Support for the amendments can be found throughout the specification and claims as originally filed. Specifically, support for the amendment to claim 1 to recite a sintered scaffold material can be found at least at page 5, lines 1-5 of the specification. Support for the amendment to claim 1 to recite a porosity of between about 50 volume % and about 90 volume % can be found in claim 22 as originally filed. Support for the amendment to claim 6 to recite a sintered glass scaffold can be found at least at page 6, lines 4-6. Claim 6 was further amended grammatically. Claims 21 and 22 were amended to remove their dependency to claim 1, and to modify their grammar. The amendments presented herein add no new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

II. Claims 1-8, 11, 12, 15-20, 31-33 and 35-37 Are Novel Over Dunn et al.

At page 2, paragraph 3 of the instant Office Action, claims 1-8, 11, 12, 15-20, 31-33 and 35-37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dunn et al., U.S. Patent No. 4,655,777. The Examiner is of the opinion that Dunn et al. discloses a porous composite material comprising sintered bioactive glass fibers wherein the sintering is from 600°C to 1150°C for 1 hour as per instant claims 1-5 and 17-18. The Examiner asserts that Dunn et al. discloses that the fibers are encased in a matrix of a polymer such as poly(L-lactide) as per instant claims 6-8. The Examiner further asserts that Dunn et al. discloses bioactive glass fibers as per instant claims 15, 16, 19 and 20, and that a poly(DL-lactide) film can be attached to the composite material as per instant claims 31-33. Finally the Examiner asserts that claims 3-5, 11, 12 and 23-37 are product by process claims, and that patentability is determined based on the product itself, not based on its method of production. Applicant respectfully traverses the Examiner's rejections. Applicant respectfully submits that for a reference to anticipate a claim, the reference must teach each and every element of the claim.

Amended claim 1 is directed to a sintered scaffold material comprising glass or ceramic fibers, wherein the scaffold material has a porosity of between about 50 volume % to about 90 volume %. Amended claim 6 is directed to a sintered glass scaffold comprising glass fibers, wherein the fibers have a coating of one or more biocompatible polymers or copolymers.

The scaffolds of the present invention are comprised of fibers that are sintered together, resulting in the formation spaces, i.e., pores, between the attached portions of the fibers (page 7, lines 14-32). Accordingly, Applicant's claimed sintered scaffolds are highly porous (up to 90 volume %) (page 7, lines 32-34 of the specification). The porosity of Applicant's scaffolds allows bone ingrowth within the scaffold, and dissolution of the scaffold at a controlled rate, thus

allowing the ingrown bone to replace the scaffold (page 1, line 32 to page 2, line 2; page 4, line 34 to page 5, line 1; page 7, lines 9-11; page 9, lines 18-20). Applicant's claimed scaffolds also have a compression strength that is suitable for load bearing purposes, whereas conventional ceramic implants are typically too hard and brittle to be suitable for load bearing uses (page 2, lines 14-15 and page 7, lines 34-36 of the specification). Because of such physical properties, Applicant's sintered scaffolds are osteoconductive and are well-suited for filling defects or hollow portions of bone for surgical and orthopaedic treatments (page 1, lines 13-14 and page 7, lines 30-34).

Dunn et al. is directed to biodegradable prostheses comprising reinforcing fibers and a biodegradable polymer matrix (abstract). Dunn et al. teaches fibers made from materials such as ceramic and biodegradable glass, and teaches that these fibers are added to a biodegradable polymer matrix to create biodegradable composites (column 9, lines 41-43). There is no teaching or suggestion that the matrices of Dunn et al. are porous, let alone have a porosity of between about 50 volume % and about 90 volume %, as required by claim 1.

Dunn et al. teaches that their implants are fracture-fixation plates and devices (column 3, lines 16-19) that serve to "maintain fractured segments in close approximation for the promotion of primary union and healing" (column 1, lines 19-21). Thus, the devices of the Dunn reference are to provide support to the healing bone, not function as a matrix in which new bone can grow. Accordingly, Dunn et al. is not concerned with composites having physical properties that allow bone ingrowth, such as porosity. Instead, the prostheses of Dunn et al. are biodegradable composites designed to have "structural rigidity" (column 9, lines 44-46).

Furthermore, Dunn et al. fails to teach or suggest Applicant's claimed ***sintered*** scaffolds. As discussed above, it is the sintering of the scaffold that produces a high porosity, imparting the

implant with properties such as an appropriate rate of dissolution and a physical structure that is beneficial for bone ingrowth. Although Dunn et al. teaches ***individual*** sintered ceramic fibers (such as β-whitlockite (TCP)) (column 5, lines 25-29; column 6, lines 60-65), Dunn et al. neither teaches nor suggests a sintered ***scaffold*** comprised of ceramic fibers. Dunn et al. also fails to teach or suggest a sintered glass scaffold comprising glass fibers, as required by instant claim 6.

As Dunn et al. fails to teach each and every element of Applicant's claims, Applicant requests that the rejection of claims 1-8, 11, 12, 15-20, 31-33 and 35-37 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

III. Claims 1, 13, 14, 29 and 34 Are Novel Over Ylanen et al.

At page 3, paragraph 4 of the instant Office Action, claims 1, 13, 14, 29 and 34 stand rejected under 35 U.S.C. §102(e) as being anticipated by Ylanen et al., U.S. Patent No. 6,248,344. The Examiner asserts that Ylanen et al. discloses a porous composite comprising sintered bioactive glass that promotes bone growth as per instant claims 1 and 34. The Examiner also asserts that this reference discloses glass as per instant claims 13 and 14, and a compression strength as per instant claim 29. Applicant respectfully traverses the Examiner's rejections based on the amended claims now presented. Applicant respectfully submits that for a reference to anticipate a claim, the reference must teach each and every element of the claim.

Ylanen et al. fails to teach each and every element of Applicant's claimed invention. Ylanen et al. is directed to composite materials comprising sintered glass ***spheres***. Ylanen et al. is not directed to a sintered glass scaffold comprising glass ***fibers***, as claimed by Applicant. Furthermore, Ylanen et al. fails to teach or suggest a sintered glass scaffold having a porosity of between about 50 volume percent to about 90 volume percent.

Applicant respectfully submits that sintered scaffolds comprising glass fibers have very different properties than sintered scaffolds comprising glass spheres. One difference is scaffolds comprised of glass fibers have a much higher degree of porosity than is achievable with sintered scaffolds comprising glass spheres, such as those of Ylanen et al. (page 2, line 36 to page 3, line 2 of the specification). A high degree of porosity is a particularly useful physical property that can lead to faster healing of bone when used as an implant (page 5, lines 32-34 of the specification). Applicant also teaches that sintered glass fibers create "a higher strength scaffold" than sintered glass microspheres (page 5, line 28 of the instant specification). In contrast, sintered blocks comprising sintered glass microspheres are brittle and break easily upon load bearing (page 2, lines 35-36). Thus, Applicant's scaffolds are more suitable for load-bearing applications. Furthermore, the sintered scaffolds of Applicant's claimed invention provide a larger amount of reacting surface because they have a larger surface area than sintered scaffolds comprising glass spheres (page 6, lines 1-6 of the specification). Thus, Applicant's claimed scaffold is physically very different from the materials of Ylanen et al.

As Ylanen et al. fails to teach each and every element of Applicant's claims, Applicant requests that the rejection of claims 1, 13, 14, 29 and 34 under 35 U.S.C. §102(e) be reconsidered and withdrawn.

IV. Claims 1, 9, 10, 21 and 22 Are Patentable Over Dunn et al.

At page 4, paragraph 6 of the instant Office Action, claims 1, 9, 10, 21 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., U.S. Patent No. 4,655,777. The Examiner admits that Dunn et al. does not disclose the thickness of the coating and the porosity of the composite material as per instant claims 9, 10, 21 and 22. The Examiner

instead asserts that it would have been obvious to one of ordinary skill in the art to have a coating on the bioactive glass fibers from about 1 micron to 200 microns in order to prevent breakage of the fibers.

Applicant respectfully traverses the Examiner's rejections. To render a claim obvious, all the claim limitations must be taught or suggested by the prior art. As discussed above, Dunn et al. fails to teach or suggest ***sintered*** scaffolds, as required by the instant claims. Dunn et al. also fails to teach or suggest a ***porosity*** of between about 50 volume % and about 90 volume %, as required by amended claim 1, and fails to teach or suggest sintered glass scaffolds, as required by claim 6.

The Examiner asserts that the bioactive fibers disclosed in the reference are highly porous. Applicant respectfully disagrees. Instead of teaching highly porous fibers, as asserted by the Examiner, Dunn teaches quite the contrary. Dunn et al. teaches that their high strength ceramic fibers have "[g]reater densification and the ***reduction in void volume***" which produces ceramic products having "greater strength and structural rigidity" (column 3, lines 16-19, and column 4, lines 33-36, emphasis added), and that a "***void-free*** ceramic fiber...gives a more durable fiber for use in polymer reinforcement" (column 8, lines 9-11, emphasis added). The Dunn reference goes on to teach that "[d]ue to the ***highly porous*** and fragile nature of the fibers produced from the ceramic powders, the preferred fibers of the present invention are glass fibers" (column 2, line 67 to column 3, line 1, emphasis added). Based on the teachings of Dunn et al., one of skill in the art would conclude that highly porous fibers would be undesirable.

The Examiner further asserts that Dunn et al. discloses a porous composite material comprising sintered bioactive glass fibers wherein the sintering temperature is from 600°C to 1150°C for 1 hour as per instant claim 1 (see column 2, lines 40-68 and column 4, lines 3-12). In

response, Applicant respectfully submits that Dunn et al. does ***not*** teach or suggest sintering bioactive glass fibers. The references to sintering at columns 2 and 4 of Dunn et al. pertain to sintered ***ceramic*** fibers, not sintered glass fibers as asserted by the Examiner. Furthermore, as discussed above, Dunn et al. does not teach sintered scaffolds. Only ***individual*** ceramic fibers are sintered. There is no suggestion to produce a sintered scaffold, and given the teachings by Dunn et al. that *less* porosity is beneficial, one of skill in the art would not be motivated make Applicant's scaffolds, which are porous.

Accordingly, Dunn et al. fails to render the claimed invention obvious. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 9, 10, 21 and 22 under 35 U.S.C. §103(a).

V. Claims 1, 6 and 23-26 Are Patentable Over Dunn et al. In View of Tormala et al.

At page 5, paragraph 7 of the instant Office Action, claims 1, 6 and 23-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn et al., U.S. Patent No. 4,655,777, in view of Tormala et al., U.S. Patent No. 6,350,284. The Examiner asserts that although the Dunn reference does not disclose that the scaffold material is a carrier for bioactive agents as per instant claims 23-26, the Tormala reference teaches a composite material comprising bioactive glass that enhances bone growth and has a favorable pore size. The Examiner further asserts that the Tormala reference teaches that the composite material can be a carrier for bioactive agents such as growth hormones and antibiotics, and that the composite material is used with bioactive agents to promote healing. The Examiner concludes that it would have been obvious to use the composite material of the Dunn reference with a bioactive agent such as an antibiotic in order to

promote bone healing as shown in the Tormala reference. Applicant respectfully traverses the examiner's rejection.

As discussed above, Dunn et al. fails to teach or suggest the claimed invention. Tormala et al. fails to cure the deficiencies of Dunn et al.

Tormala et al. neither teaches nor suggests Applicant's claimed scaffold. Tormala et al. is directed to cranial implants comprising a layered composite material consisting of a plate layer and a web layer (abstract). Tormala teaches that the web layer may include bioactive glass fibers (column 5, lines 37-38). Nowhere does Tormala et al. teach or suggest the claimed sintered scaffolds. Furthermore, Tormala does not teach or suggest Applicant's claimed porosity volume percent.

Accordingly, the combination of Dunn et al. and Tormala et al. fails to render the claimed invention obvious. Therefore, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 6 and 23-26 under 35 U.S.C. §103(a).

VI. CONCLUSION

Having addressed all outstanding issues, Applicant respectfully requests entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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